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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,728	10/25/2001	Roberto Fagnani	71726 / 6776	3521

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EXAMINER	
LUNDGREN, JEFFREY S	
ART UNIT	PAPER NUMBER
1639	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/054,728	FAGNANI ET AL.	
	Examiner	Art Unit	
	Jeff Lundgren	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-14,17,18,31-36 and 38-46* is/are pending in the application.

4a) Of the above claim(s) *8,11-14,36,38-40,44 and 45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-7,9,10,17,18,31-35,43 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1, 3, 5-14, 17, 18, 31-36 and 38-46 are pending in the instant application; claims 8, 11-14, 36, 38-40 and 44-45 are withdrawn; claims 1, 3, 5-7, 9, 10, 17, 18, 31-35, 43, and 46 are the subject of the Office Action below.

Claim Rejections - 35 USC § 112 - New Matter Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5-7, 9, 10, 17, 18, 31-35, 43, and 46, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, because the claims contain new matter. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the claims have the limitation "flat top" which is neither supported literally in the specification, or adequately by way of example.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The rejection of claims 1, 3, 5-7, 9, 10, 16, 17, 31-35 and 46, under 35 U.S.C. 103(a) as being unpatentable over Sundberg *et al.* (US Patent 5,624,711) and Braatz *et al.* (US Patent 5,169,720), is maintained.

Contrary to Applicants allegations, Sundberg does disclose derivatized supports with an array of ligands (see e.g. Abstract; col. 1, lines 6-14 and 64-67; col. 2, lines 15-37). The derivatized supports comprise a polymer-coated support (refers to instant claimed solid substrate) and an array of ligands such as peptides (refers to instant claimed binding entity/protein binding entities and instant claim 9)(see e.g. col. 5, lines 25-35; col. 5, line 66 thru col. 6, line 10; col. 6, lines 18-35; col. 13, lines 46-52). The polymer-coated support comprises a polymer films that provide a porous three-dimensional matrix functionalized with reactive groups, and greater solvent compatibility and flexibility of the reaction site for attachment (see e.g. col. 13, lines 49-60). Accordingly, the polymer films of Sundberg is obvious over the instant claimed hydrogel since the definition of the polymer films would encompass the definition of hydrogel as define in the instant specification (see instant specification pg. 10, lines 16-18). The support's surface comprises a diverse array of ligands is produced on the substrate wherein the ligands include polypeptides (refers to instant claimed different binding entity/protein) and predefined regions such as wells to physically separate synthesis regions for different polymers (refers to instant claimed 'discrete locations')(see e.g. col. 5, line 66 thru col. 6, line 10; col. 6, lines 18-35; col. 11, lines 20-27)(see e.g. col. 5, lines 36-48; col. 6, lines 56-59; col. 9, lines 43-53). The polymer coating includes polyurethanes or polyethylene glycol and isocyanate functional group for the attachment of the ligands (refers to instant claimed isocyanate-functional polymer/urethane linkages, and instant claims 2, 3, 10, 17, and 32)(see e.g. col. 5, lines 25-35; col. 11, lines 59-62). In addition, the ligands can attach to the derivatized supports through a linking molecule (refers to instant claim 10)(see e.g. col. 12, lines 5-16; col. 12, lines 38-41). Regarding the thickness of the gel, Sundberg states:

> "In this case, the thickness of the resulting gel is equivalent to that of the spacers used (***13 or 50 microns***)."

Sundberg, col. 25, lines 39 and 40 (emphasis added).

The supports of Sundberg differ from the presently claimed invention by failing to include a polymer comprising an isocyanate-capped polyurethane prepolymer and the polyethylene glycol having a molecular weight of at least about 5000.

Braatz discloses polymer-coated devices (see e.g. Abstract; col. 2, lines 46-64; col. 3, lines 20-32). The polymer coatings comprise isocyanate end-capped prepolymer oxyethylene based diols or glycols (see e.g. col. 2, lines 46-64; col. 3, lines 20-32; col. 3, line 43 thru col. 4, line 44). The molecular weight of the oxyethylene based diols or glycols range from 7000 to 30,000 (col. 3, line 43 thru col. 4, line 44; col. 15, line 65 thru col. 16, line 37). The isocyanate include compounds such as toluene diisocyanate (see e.g. col. 5, lines 3-21). The polymer coatings are transparent and coated onto a substrate (col. 11, lines 30-34; col. 11, line 64 thru col. 12, line 19). In addition, Braatz et al. disclose that the thickness of the polymer coatings depend on the prepolymer concentration such that the thickness of the polymer coatings substrate would constitute obvious variations in parameters which are routinely modified in the art (see e.g. col. 9, lines 48-59). Thus, the claimed thickness of claims 4, 5, and 33 would be a choice of experimental design and is considered within the purview of the cited prior art of Braatz.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a polymer comprising an isocyanate-capped polyurethane prepolymer and the hydrogel having a molecular weight of at least about 5000 as taught by Braatz et al. in the supports of Sundberg et al. One of ordinary skill in the art would have been motivated to include a polymer comprising an isocyanate-capped polyurethane prepolymer and the hydrogel having a molecular weight of at least about 5000 in the supports of Sundberg et al. for the advantage of providing a class of hydrated polymers for which ease of preparation and handling is combined with desirable properties permitting a wide range of end uses (Braatz: col. 2, lines 65-68) since both Sundberg et al. and Braatz et al. disclose a support comprises coated polymers with hydroxyl functional group such as polyethylene glycol (Sundberg: col. 15, lines 21-25; Braatz: col. 4, lines 16-22). In addition, Sundberg et al. disclose that surfaces can be designed and prepared for optimum properties in a particular assay (Sundberg: col. 14, lines 2-6) and as a result the type of polymer use would be a choice of experimental design and is

considered within the purview of the cited prior art. Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of Sundberg et al. and Braatz et al. because Braatz et al. disclosed by example the success of coating surfaces with a polymer comprising an isocyanate-capped polyurethane prepolymer (Braatz: col. 19, line 47 thru col. 20, line54).

Therefore, the combined teachings of Sundberg and Braatz render the product of the instant claims *prima facie* obvious.

The rejection of claims 1, 3, 5-7, 9, 10, 16-18, 31-35, 41-43 and 46, are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. (US Patent 6,406,921) and Braatz et al. (US Patent 5,169,720), as now evidenced by Sundberg *et al.* (US Patent 5,624,711), is maintained in modified form.

Contrary to Applicants' allegations, Wagner does disclose an array of proteins comprising a plurality of patches in discrete, known regions on a substrate, where the protein has different, known sequence is immobilized on each patch and the method of making an array of protein capture agents (see e.g. Abstract; col. 3, lines 26-29; col. 3, lines 44-47; col. 3, lines 56-58; col. 6, lines 45-52; col. 7, lines 17-19; col. 8, lines 10-17). The array comprises of a monolayer (refers to instant claimed hydrogel) on the surface of the substrate and the proteins are immobilized on the monolayer (see e.g. col. 8, lines 10-17; col. 11, lines 15-28 and 39-53). The monolayer comprises the formula of X-R-Y wherein X is the functional group that binds to the surface of the substrate, R is a hydrocarbon chain with the hetero groups such as –(OCH2CH2)n- with n =1-20, and Y is the functional group that binds to the protein such as isocyanate (see e.g. col. 8, lines 10-17; col. 10, lines 10-26; col. 11, lines 15-28 and 39-53). Moreover regarding the claimed thickness of the hydrogel (claims 4, 5, and 37), the thickness of the hydrogel would be a choice of experimental design and is considered within the purview of the cited prior art since Wagner et al. disclose that the monolayer can be of any thickness on the substrate (see e.g. col. 5, lines 15-26). Additionally, the protein can be attached to the Y functional group via an affinity tag (refers to instant claimed intermediate agent) or a reagent such as nitrilotriacetic acid (refers to instant claim 43)(see e.g. col. 11, lines 15-28; col. 11, lines 39-46; col. 12, line 59 thru col. 13,

line 12). The type of protein includes enzyme and antibodies (see e.g. col. 7, lines 34-47). The substrate comprise patterned such as walls (see e.g. col. 9, lines 55-64).

The support of Wagner differs from the presently claimed invention by failing to a polymer comprising an isocyanate-capped polyurethane prepolymer.

Braatz et al. disclose polymer-coated devices (see e.g. Abstract; col. 2, lines 46-64; col. 3, lines 20-32). The polymer coatings comprise isocyanate end-capped prepolymer oxyethylene based diols or glycols (see e.g. col. 2, lines 46-64; col. 3, lines 20-32; col. 3, line 43 thru col. 4, line 44). The molecular weight of the oxyethylene based diols or glycols range from 7000 to 30,000 (col. 3, line 43 thru col. 4, line 44; col. 15, line 65 thru col. 16, line 37). The isocyanate include compounds such as toluene diisocyanate (see e.g. col. 5, lines 3-21). The polymer coatings are transparent and coated onto a substrate (col. 11, lines 30-34; col. 11, line 64 thru col. 12, line 19). In addition, Braatz disclose that the thickness of the polymer coatings depend on the prepolymer concentration such that the thickness of the polymer coatings substrate would constitute obvious variations in parameters which are routinely modified in the art (see e.g. col. 9, lines 48-59). Thus, the claimed thickness of claims 4, 5, and 33 would be a choice of experimental design and is considered within the purview of the cited prior art of Braatz.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to a polymer comprising an isocyanate-capped polyurethane prepolymer as taught by Braatz in view of Wagner. One of ordinary skill in the art would have been motivated to a polymer comprising an isocyanate-capped polyurethane prepolymer in the support of Wagner for the advantage of providing a class of hydrated polymers for which ease of preparation and handling is combined with desirable properties permitting a wide range of end uses (Braatz: col. 2, lines 65-68) since both Wagner and Braatz disclose a support comprises coated polymers with hydroxyl functional group such as polyethylene glycol (Wagner: col. 12, lines 31-38; Braatz: col. 4, lines 16-22). In addition, Wagner disclose that there are many possible design choices with regard to the type of coating on the substrate (Wagner: col. 8, lines 34-38) and as a result the type of polymer use would be a choice of experimental design and is considered within the purview of the cited prior art (see Sundberg). Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of Wagner and Braatz because Braatz disclosed by example the success of coating surfaces with a

polymer comprising an isocyanate-capped polyurethane prepolymer (Braatz: col. 19, line 47 thru col. 20, line54).

Therefore, the combined teachings of Wagner and Braatz do render the product of the instant claims *prima facie* obvious.

Conclusions

No claim is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If Applicants should amendment the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (*e.g.*, if the amendment is not supported *in ipsis verbis*, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeff Lundgren whose telephone number is 571-272-5541. The Examiner can normally be reached from 7:00 AM to 5:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Schultz, can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JSL/

J. DOUGLAS SCHULTZ, PH.D.
SUPERVISORY PATENT EXAMINER